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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,548	10/18/2001	Dongfang Liu	M0656.70070US00	7782

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WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/982,548

Applicant(s)

LIU ET AL.

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43, 58, 116-121, 204, 206-209, 211-213, 223-232 and 235-237 is/are pending in the application.
- 4a) Of the above claim(s) 232, 237 and 238 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43, 116, 121, 204, 206, 208, 226, 227, 229-231, 235 and 236 is/are rejected.
- 7) ☒ Claim(s) 58, 117-120, 204, 207, 209, 211-213, 223-225 and 228 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892). | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed 2/12/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 43, 58, 116-121, 204, 206-209, 211-213, and 223-232 have been amended.

Claims 235-238 have been added

Claims 1-42, 44-57, 59-115, 122-203, 205, 210, 214-222, and 233-234 have been canceled.

Remarks drawn to rejections of Office Action mailed 8/8/2006 include:

112 2nd paragraph rejections: which have been maintained for reasons of record.

102(b) rejection: which has been overcome based on applicants arguments and has been withdrawn.

An action on the merits of claims 43, 58, 116-121, 204, 206-209, 211-213, 223-232, and 235-237 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Election/Restrictions

Newly submitted claims 237-238 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims would have fallen in non-elected group I of the restriction requirement mailed on 12/29/2005. moreover, it is noted that claim 232 would also have fallen into this non-

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elected group, as such, any rejections/arguments drawn to these methods will be addressed upon rejoinder, if that is to occur during prosecution.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 232 and 237-238 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claims 235-236 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “heparin-like glycosaminoglycan” in every claim which is silent to how the molecule must be like heparin, is a relative term which renders the claims indefinite, and therefor the rejection is maintained for reasons of record. The term is not defined by the claims, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. How must another compound be like heparin to be considered “heparin-like”? Must it have the same properties, be the same size, have the same functional groups, comprise the same linking groups?

Applicants argue that the term “heparin-like glycosaminoglycan” is definite. Applicants state that the ‘504 patent recites a definition which is consistent with that provided by applicants, but merely uses different terms to define the phrase. This is not convincing. The ‘504 patent defines the term differently, as such, there is no consistent

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definition in the art for “heparin-like-glycosaminoglycan”. It is unclear how applicants can argue that definitions using non-analogous terms are the same, as hexosamine is not the same scope as glucosamine. Glucosamine is a hexosamine, however, many other compounds are hexosamines which are not glucosamine, so how can these be considered to be the same? This rejection is maintained as the art does NOT provide a consistent definition for the phrase in question, and applicants have not defined their term in clear and concise terms as required by 112 2nd paragraph.

Claim Rejections - 35 USC § 102

Claims 43, 116, 121, 204, 206, 208, 226, 227, 229-231, and 235 are rejected under 35 U.S.C. 102(b) as being anticipated by Edelman et al. (US 5,527,532).

The ‘532 patent discloses dry unformulated heparin particles having a diameter of less than 180 microns (see sentence bridging columns 6-7). Moreover, it is noted that while the ‘532 patent is silent to the tap densities, however, since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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Conclusion

Claims 58, 117-120, 204, 207, 209, 211-213, 223-225, and 228 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
May 27, 2007
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